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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,891	01/02/2002	Jeffrey T. Borenstein	62030(51588)	8813

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,891	BORENSTEIN ET AL	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-37* is/are pending in the application.

4a) Of the above claim(s) *27 and 33-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-26 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 1/6/05 amended the title and abstract and claims 1, 25, 28 and 32, and canceled claims 3.

An Information Disclosure Statement of 1/5/05 has not been considered since form PTO/SB/08 and copies of references stated to have been submitted with the statement have not been received.

Claims 27 and 33-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/21/04.

Claims examined on the merits are 1, 2, 4-26 and 28-32.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (6,143,293) in view of Vacanti et al (6,139,574) and Mastrangelo et al (6,136,212), and if necessary in further view of Cima et al (5,518,680) or Marra et al (6,165,486) for reasons in the previous office action of 10/6/04 and for reasons herein.

The claims are drawn to a multilayer device containing a first layer for attachment and culturing of cells and containing a pattern of microchannels of about 10 to 50 microns in diameter, and a second

layer for attachment and culturing of cells, and the first and second layers being fastened together.

Weiss et al disclose a scaffold containing multiple layers fastened together for cell culture that is the same as presently claimed except for the presence of microchannels.

Vacanti et al disclose a scaffold for tissue regeneration containing interconnected pores.

Mastrangelo et al disclose producing microfluidic devices containing microchannels.

It would have been obvious to provide a layer of the scaffold of Weiss et al with interconnecting microchannels as suggested by Vacanti et al disclosing a scaffold having interconnected pores and Mastrangelo et al disclosing producing microfluidic devices having microchannels. Microchannels in the scaffold of Weiss et al would have been expected to be advantageous for the same type of reason that Mastrangelo et al found such channels to be advantageous. Providing microchannels about 10 to 50 microns in diameter would have been a matter of obvious choice depending on the size of cells desired to enter the channels, would have been a matter of individual preference well within the skill of the art. If needed, Cima et al or Marra et al would have further suggested scaffold structure. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The methods of claims 25, 26 and 28-32 would have been obvious methods of making the scaffold in view of the methods disclosed by the references.

Response to Arguments

Applicant's arguments filed 1/6/05 have been fully considered but they are not persuasive.

Applicants urge that microchannels of about 10 to 50 microns in diameter as now required by the references are not suggested by the references. However, the scaffold of Weiss et al can contain pores of 200-400 microns (col 2, line 60) and the matrix of Vacanti et al can have pores of 5-80 microns (col 15, line 39) or 10-20 microns (col 12, line 61) and channels of 60-300 microns (col 17, line 18). Thus, it would have been apparent to the ordinary skilled artisan that pore size can vary, and will depend on preferred size desired for a particular use or cell size to enter the scaffold. The specification discloses that the channel size can be 5-500 microns (paragraph 78), and no critically has been established in using a channel size of 10-50 microns. The specification discloses that this channel size is merely a size for endothelial cells to enter. Weiss et al disclose that current approaches use a type of scaffold material to promote one type cell growth. When the cell type is endothelial cells, it would have been obvious to select a channel size for these cells instead of for bone cells as in Weiss et al. Selecting a particular channel size merely because the size allows a certain cell to enter would have been obvious and within the ordinary skill of the art.

Conclusion

This application contains claims 27 and 33-37 drawn to an invention nonelected with traverse in the reply of 7/21/04. A

complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
3/26/05